

### Remarks

With the current cancellation of claims 7-38 as non-elected claims as a result of a Restriction Requirement, and the previous cancellation of claim 2, claims 1 and 3-6 are pending.

Descriptive support for the amendments can be found the specification at page 1, lines 22-24; page 6, lines 8 and 11; page 12, lines 10 and 19; page 13, lines 7, 22 and 26; page 14, lines 4, 8, 26, 31 and 32; page 15, lines 1-5 and 21-23.

### Applicant's Statement of Substance of Examiner Interview

The undersigned would like to thank Examiner Navarro for the courtesy extended in the telephone interview conducted on December 28, 2010.

Prior Art Discussed: Robinson et al. (2001) article.

Claims Discussed: Claim 1

Agreement Reached: None

In the interview, the insertion of the word "isolated" in the preamble of claim 1 was discussed concerning a potential way of dealing with the rejection under 35 U.S.C. 101. Examiner Navarro indicated that the insertion should overcome the rejection. The undersigned discussed with Examiner Navarro regarding the disclosure of the Robinson et al. (2001) article, and the alternating anaerobic and aerobic conditions. The undersigned indicated that claim amendments would be considered to deal with the rejections under 35 U.S.C. 102 and 112.

### Claim Rejections -- 35 U.S.C. 101

Applicant respectfully traverse the rejection of claims 1 and 3-6 under 35 U.S.C. 101 as directed to non-statutory subject matter.

The Office Action rejects claims 1 and 3-6 as directed to non-patentable subject matter because the Office Action asserts that the culture of morphotes according to claims 1 and 3-6 could be found in nature because the Office Action alleged that the claims

encompassed morphotes directly obtained from mammalian tissue without being subjected to some procedure not found in nature. It appears that the Examiner was confused with the term “morphotes.” Furthermore, near the bottom of page 9 of the Office Action, the Examiner stated that the exhibition of multicellular self organization into a multicellular mammalian tissue like pattern when cultured in vitro was merely an intended use of the claimed morphote and not accorded any patentable weight. Applicant disagrees that the multicellular self organization is merely an intended use and does not deserve any patentable weight. However, in order to advance prosecution without acquiescence with the rejection reasoning, applicant has replaced “morphotes” with *Staphylococcus epidermidis* in claim 1 and amended claim 1 to make the exhibition of the multicellular mammalian tissue like pattern as a recited feature of the in vitro culture of claim 1. Applicant notes that *Staphylococcus epidermidis* found in nature does not form any in vitro culture exhibiting the multicellular mammalian tissue like pattern. For instance, *Staphylococcus epidermidis* found in nature does not form an in vitro culture exhibiting a multicellular mammalian tissue-like pattern such as

- (a) sheet-like tissue-level multicellular self-organization;
- (b) capillary-like-tissue; or
- (c) trabecular (spongy) bone-like tissue.

Thus, the subject matter of the amended claims 1 and 3-6 is not a product of nature. Withdrawal of the rejection is requested.

Claim Rejection -- 35 U.S.C. 112, First Paragraph

Applicant respectfully traverses the rejection of claims 1 and 3-6 for failing to comply with the written description requirement. The Examiner rejected claims 1 and 3-6 for failing to comply with the written description requirement because the scope of the claims includes numerous structural variants without any disclosure of the distinguishing attributes shared by the members of the genus, and yet the specification discloses only one

species (the culture of *Staphylococcus epidermidis* isolated by the method of Example 1). Without acquiescence with the reasoning of the rejection, claim 1 has been amended by replacing “morphotes” with *Staphylococcus epidermidis*. There is no evidence that the applicant did not have possession of the claimed in vitro culture of *Staphylococcus epidermidis* according to the amended claim 1 when the present patent application was filed. The embodiments of the claimed invention share the feature that the claimed in vitro cultures all exhibit a multicellular mammalian tissue-like pattern. Thus, applicant contends that the claimed invention fulfills all the requirements of 35 U.S.C. 112. The rejection of the claims under 35 U.S.C. 112 should be withdrawn.

Claim Rejections -- 35 U.S.C. 102(b)

I. Applicant respectfully traverses the anticipatory rejection of claims 1 and 3-6 over Wainwright (*Medical Hypotheses*, vol. 60, pp. 290-292, Feb. 2003). The Office Action asserts that Wainwright anticipates claims 1-6 because Wainwright isolated a culture of bacteria from mammalian tissue, which culture superficially appeared fungal. The Office Action asserts that the “appeared fungal” observation made by Wainwright is sufficient to meet the limitation of “morphologic characteristic of a eukaryotic.” Applicant disagrees. Appearing fungal is not the same as multicellular, mammalian tissue-like pattern recited in claim 1. The Office Action alleges that the “intended use” of tissue level multicellular self organization is necessarily present in the bacteria isolated by Wainwright (page 10, last sentence, first paragraph of the Office Action). Applicant maintains that having a superficial fungal appearance under low magnification does not imply that the bacteria isolated by Wainwright necessarily has the multicellular, mammalian tissue-like pattern recited in claim 1.

In addition, Wainwright does not disclose any in vitro culture of *Staphylococcus epidermidis*. In fact Wainwright admits that the organism isolated is likely to be a strain of *Bacillus licheniformis* (see Summary, p. 290).

Thus, applicant contends that Wainwright fails to anticipate claims 1 and 3-6.

II. Applicant respectfully traverses the anticipatory rejection of claims 1 and 3-6 over Robinson. The Examiner asserted that Robinson anticipates claims 1 and 3-6 because Robinson isolated a culture of pleomorphic bacterium from mammalian tissue, which also expressed both human genes/proteins. Applicant disagrees that Robinson anticipates claims 1 and 3-6.

Robinson isolated a culture of bacteria that showed fungal-like morphology (see Figure 1c). However, Robinson does not disclose that the bacterial culture having fungal-like morphology is an in vitro culture of *Staphylococcus epidermidis*. In addition, there is no evidence that the culture of bacteria isolated by Robinson exhibits a multicellular mammalian tissue-like pattern when cultured in vitro. Thus, the anticipatory rejection of claims 1 and 3-6 should be withdrawn.

In the event that the filing of this Response is not timely, applicant petitions for an appropriate extension of time. The Examiner is invited to contact the undersigned at (202) 220-4200 to discuss any matter concerning this application. The Office is authorized to charge any fees related to this communication to Deposit Account No. 11-0600.

Respectfully submitted,

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